

**REPORT OF
AIR POLLUTION SOURCE TESTING
OF AN ETHYLENE OXIDE EMISSION-CONTROL SYSTEM
OPERATED BY STERIGENICS U.S., LLC.
IN SANTA TERESA, NEW MEXICO
ON DECEMBER 12, 2012**

Submitted to:

**NEW MEXICO ENVIRONMENT DEPARTMENT
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1.0 INTRODUCTION

On December 12, 2012, ECSi, Inc. performed air pollution source testing of an ethylene oxide (EtO) emission-control device operated by Sterigenics U.S., LLC. in Santa Teresa, New Mexico. The control device tested was a Ceilcote packed tower scrubber emission-control system, which is currently used to control emissions from thirteen EtO sterilizer vacuum pumps. The purpose of the testing program was to demonstrate continued compliance with EPA requirements under the current National Emissions Standards for Hazardous Air Pollutants (NESHAP), and with the requirements of the New Mexico Environment Department (NMED).

2.0 EQUIPMENT

The EtO gas-sterilization system is comprised of thirteen commercial sterilizers, all discharging through dry screw or liquid-ring vacuum pumps to a packed-tower acid scrubber emission control device. Two aeration rooms and nine aeration cells are all discharged to Donaldson Abator catalytic oxidizer emission-control device. The gas-sterilization and emission-control equipment consists of the following:

- Thirteen Gas Sterilizers, each comprised of a steam-heated sterilization chamber (varying in size from 13-30 pallet capacity), a dry screw or liquid ring recirculating vacuum pump chamber evacuation system ("chamber vacuum vent"), and a backdraft valve ("chamber exhaust vent");
- Two aeration rooms and nine aeration cells, each comprised of a heated aeration chamber and a chamber exhaust system

Sterilizer vacuum pump emissions are controlled by:

- One Ceilcote packed-tower chemical scrubber, equipped with a packed reaction/interface column, a scrubber fluid recirculation system, a scrubber fluid reaction/storage tank, and a dedicated blower exhaust system.

Aeration cell/room emissions are controlled by:

- One Donaldson EtO Abator catalytic oxidizer, 20,000 SCFM, equipped with a prefilter, a gas-fired heater, an exhaust gas heat exchanger, a reactive catalyst bed, and an exhaust blower.

3.0 TESTING

EtO source testing was conducted in accordance with the procedures outlined in USEPA CFR40, Part 63.365. EtO emissions monitoring was conducted simultaneously at the inlet and outlet of the packed tower scrubber during the first chamber evacuation of the sterilizer exhaust phase of one of the thirteen sterilizers representing the maximum inlet flow to the scrubber. A total of three exhaust-phase test runs were performed.

Exhaust phase testing with one sterilizer discharging to the scrubber at a time represents worst-case conditions for demonstration of control efficiency compliance. At this lower inlet loading, the scrubber must perform at its maximum efficiency to achieve outlet EtO concentrations low enough to demonstrate compliance.

During the first chamber evacuation of the exhaust phase, EtO emissions to the inlet of the packed tower scrubber were determined using the Ideal Gas Law and the chamber conditions at the beginning and at the end of the first chamber evacuation. During the first chamber evacuation of the exhaust phase, EtO emissions from the outlet of the packed tower scrubber were determined using direct source sample injection into the GC.

All exhaust phase testing was conducted during normal process load conditions, but with an empty sterilization chamber to facilitate inlet mass calculation and the performance of multiple test runs. The testing program was conducted in accordance with the procedures outlined in the following sections.

4.0 RULE/COMPLIANCE REQUIREMENTS

The EtO gas-sterilization system at Sterigenics U.S., LLC. was tested to determine compliance with the current federal EPA National Emissions Standard for Hazardous Air Pollutants (NESHAP) for ethylene oxide, and with NMED requirements. The current testing was performed to demonstrate continued compliance with the following requirements:

- The emissions from the sterilizer vacuum pumps must be discharged to control equipment with an EtO emission-reduction efficiency of at least 99.0% by weight.

Testing is required to demonstrate compliance with these requirements. Source testing of the emission-control device is required initially, and may be required periodically thereafter, in accordance with NMED requirements.

5.0 TEST METHOD REFERENCE

5.1 INTRODUCTION

EtO source testing was conducted in accordance with the procedures outlined in USEPA CFR40, Part 63.365. EtO emissions monitoring was conducted simultaneously at the inlet and outlet of the packed tower scrubber during the first chamber evacuation of the sterilizer exhaust phase of one of the thirteen sterilizers representing the maximum inlet flow to the scrubber. A total of three exhaust-phase test runs were performed.

Exhaust phase testing with one sterilizer discharging to the scrubber at a time represents worst-case conditions for demonstration of control efficiency compliance. At this lower inlet loading, the scrubber must perform at its maximum efficiency to achieve outlet EtO concentrations low enough to demonstrate compliance.

During the first chamber evacuation of the exhaust phase, EtO emissions to the inlet of the packed tower scrubber were determined using the Ideal Gas Law and the chamber conditions at the beginning and at the end of the first chamber evacuation. During the first chamber evacuation of the exhaust phase, EtO emissions from the outlet of the packed tower scrubber were determined using direct source sample injection into the GC.

All exhaust phase testing was conducted during normal process load conditions, but with an empty sterilization chamber to facilitate inlet mass calculation and the performance of multiple test runs. The testing program was conducted in accordance with the procedures outlined in the following sections.

Operation and documentation of process conditions was performed by personnel from Sterigenics, using existing monitoring instruments installed by the manufacturer on the equipment to be tested. This parametric monitoring data is attached as Appendix G.

5.2 VOLUMETRIC FLOW MEASUREMENT

Exhaust gas flow at the outlet of the scrubber was determined by 40 CFR 60, Appendix A, Method 2, using an s-type pitot tube and an inclined-oil manometer. Sampling ports were located in accordance with 40 CFR 60, Appendix A, Method 1. The test ports were located far enough from any flow disturbances to permit accurate flow measurement.

Temperature measurements were obtained from a type K thermocouple and thermometer attached to the sampling probe. Exhaust gas composition was assumed to be air and water vapor. Water vapor saturation was assumed, and a default value of 3 percent was used as a worst case estimate for flow determination.

5.3 CONTROL EFFICIENCY AND MASS EMISSIONS MEASUREMENT

During the first chamber evacuation of the sterilizer exhaust phase, the mass emissions of EtO vented to the inlet of the scrubber were determined using the procedures outlined in CFR40, Part 63.365. This method allows the determination of the mass of EtO vented to the inlet of the scrubber through calculations based on the Ideal Gas Law and using the conditions (pressure, temperature, volume) of the sterilization chamber immediately after it has been charged with sterilant gas, and upon conclusion of the first chamber evacuation of the exhaust phase.

The mass of EtO vented to the inlet of the scrubber during the first chamber evacuation of the exhaust phase was determined by calculating the mass of EtO present in the chamber after the first chamber evacuation and subtracting it from the mass of EtO present in the chamber after it had been charged with sterilant gas. The mass of EtO present in the chamber was calculated using Equation 1, shown below in Section 5.9.

During the first chamber evacuation of the sterilizer exhaust phase, EtO emissions from the outlet were determined using direct source sample injection into the GC. The mass of EtO emitted from the outlet was determined using Equation 2, shown below in Section 5.9. Mass-mass control-efficiency of EtO during the sterilizer exhaust phase was calculated by comparing the mass of EtO vented to the system inlet to the mass of EtO vented from the system outlet.

During the sterilization chamber exhaust phase, vented gas was analyzed by an SRI, Model 8610, portable gas chromatograph (GC), equipped with the following: dual, heated sample loops and injectors; dual

columns; and dual detectors. A flame ionization detector (FID) was used to quantify EtO emissions at the packed tower scrubber outlet.

5.4 SAMPLE TRANSPORT

Source gas was pumped to the GC at approximately 500-1000 cubic centimeters per minute (cc/min) from the sampling ports through two lengths of Teflon® sample line, each with a nominal volume of approximately 75 cubic centimeters (cc) and an outer diameter of 0.25 inch. At the outlet of the scrubber the sampling ports were located in the exhaust stack.

5.5 GC INJECTION

Source-gas samples were then injected into the GC which was equipped with two heated sampling loops, each containing a volume of approximately 2cc and maintained at 100 degrees Celsius (C). Injections occurred at approximately one-minute intervals during the sterilization chamber exhaust phase. Helium was the carrier gas for the PID.

5.6 GC CONDITIONS

The packed columns for the GC were both operated at 80 degrees C. The columns were stainless steel, 6 feet long, 0.125 inch outer diameter, packed with 1 percent SP-1000 on 60/80 mesh Carbopack B.

Any unused sample gas was vented from the GC system back to the inlet of the scrubber.

5.7 CALIBRATION STANDARDS

The FID was calibrated for mid-range ppmv level analyses using gas proportions similar to the following:

- 1) 1000 ppmv EtO, balance nitrogen
- 2) 100 ppmv EtO, balance nitrogen
- 3) 50 ppmv EtO, balance nitrogen (audit gas)
- 4) 10 ppmv EtO, balance nitrogen
- 5) 1 ppmv EtO, balance nitrogen

Each of these calibration standards was in a separate, certified manufacturer's cylinder. Copies of the calibration gas laboratory certificates are attached as Appendix F.

5.8 SAMPLING DURATION

Exhaust phase EtO measurements were taken for the entire duration of the first chamber evacuation, which was approximately 30-50 minutes. This encompassed a total sampling duration of approximately 30-50 minutes for each exhaust phase test run.

5.9 CONTROL-EFFICIENCY/MASS-EMISSIONS CALCULATIONS

The following equation was used to calculate mass of EtO discharged to the inlet of the emission-control system during the first chamber evacuation of the sterilizer exhaust phase:

EQUATION 1:

$$W_c = W_{ci} - W_{cf}$$

Where:

W_c = Weight of EtO discharged from the sterilization chamber to the emission-control system during the first chamber evacuation, pounds

$$W_{ci} = (mw)(p)(V)/(R)(T)$$

(and W_{cf})

Where:

W_{ci} = Weight of EtO present in the sterilization chamber before the first chamber evacuation, pounds

W_{cf} = Weight of EtO present in the sterilization chamber after the first chamber evacuation, pounds

MW = Molecular weight of EtO, 44.05 lb/mol

p = Percent of EtO in chamber

$$= W_s/W_i$$

Where:

W_s = Scale-measured weight of EtO charged into sterilization chamber

W_i = Calculated weight of EtO charged into sterilization chamber (@ 100%)

P = Sterilization chamber pressure (after charging/at the end of the 1st evac), psia

V	=	Sterilization chamber volume, ft ³
R	=	Gas constant, 10.73 psia·ft ³ /mol·°R
T	=	Sterilization chamber temperature (after charging/at the end of the 1st evac), °R

Note: Standard conditions are 68°F and 1 atm.

Mass emissions of EtO during the exhaust phase were calculated using the following equation:

EQUATION 2:

$$\text{MassRate} = (\text{VolFlow})(\text{MolWt})(\text{ppmv EtO}/10^6)/(\text{MolVol})$$

Where:

MassRate	=	EtO mass flow rate, pounds per minute
VolFlow	=	Corrected volumetric flow rate, standard cubic feet per minute at 68 degrees F
MolWt	=	44.05 pounds EtO per pound mole
ppmv EtO	=	EtO concentration, parts per million by volume
10 ⁶	=	Conversion factor, ppmv per "cubic foot per cubic foot"
MolVol	=	385.32 cubic feet per pound mole at one atmosphere and 68 degrees F

Results of the control-efficiency testing are presented in Section 8.0 and in Table 1.

6.0 TEST SCENARIO

During exhaust phase testing, each sterilizer was tested during normal process load conditions, but with an empty sterilization chamber to facilitate the performance of multiple test runs. A total of three exhaust-phase test runs were performed to verify the performance of the emission-control device. Testing was conducted with an effort to offer minimal disruption to the Sterigenics production schedule. The testing schedule was as follows:

- 1) Testing equipment was set up and calibrated.
- 2) An empty-chamber cycle was started in one of the sterilizers. This sterilizer was isolated for test use and designated as a test chamber.
- 3) Exhaust Phase Test Run #1 was conducted. Sampling was performed at outlet of the scrubber during the first chamber evacuation of the test chamber. During the performance of the test, only the sterilizer used for the test was allowed to discharge to the Ceilcote scrubber.
- 4) An empty-chamber cycle was started in another of the sterilizers. This sterilizer was isolated for test use and designated as a test chamber.
- 5) Exhaust Phase Test Run #2 was conducted. Sampling was performed at outlet of the scrubber during the first chamber evacuation of the test chamber. During the performance of the test, only the sterilizer used for the test was allowed to discharge to the Ceilcote scrubber.
- 6) An empty-chamber cycle was started in another of the sterilizers. This sterilizer was isolated for test use and designated as a test chamber.
- 7) Exhaust Phase Test Run #3 was conducted. Sampling was performed at outlet of the scrubber during the first chamber evacuation of the test chamber. During the performance of the test, only the sterilizer used for the test was allowed to discharge to the Ceilcote scrubber.
- 8) Post calibration check was performed, testing equipment was packed.

7.0 QA/QC

7.1 FIELD TESTING QUALITY ASSURANCE

At the beginning of the test, the sampling system was leak checked at a vacuum of 15 inches of mercury. The sampling system was considered leak free when the flow indicated by the rotameters fell to zero.

At the beginning of the test, a system blank was analyzed to ensure that the sampling system was free of EtO. Ambient air was introduced at the end of the heated sampling line and drawn through the sampling system line to the GC for analysis. The resulting chromatogram also provided a background level for non-EtO components (i.e. ambient air, carbon dioxide, water vapor) which are present in the source gas stream due to the ambient dilution air which is drawn into the emission-control device, and due to the destruction of EtO by the emission-control device which produces carbon dioxide and water vapor. This chromatogram, designated AMB, is included with the calibration data in Appendix A.

7.2 CALIBRATION PROCEDURES

The GC system was calibrated at the beginning and conclusion of each day's testing. Using the Peaksimple II analytical software, a point-to-point calibration curve was constructed for each detector. A gas cylinder of similar composition as the calibration gases, but certified by a separate supplier, was used to verify calibration gas composition and GC performance.

All calibration gases and support gases used were of the highest purity and quality available. A copy of the laboratory certification for each calibration gas is attached as Appendix F.

8.0 TEST RESULTS

The Ceilcote scrubber demonstrated an EtO control efficiency of 99.954 percent. In accordance with EPA and NMED requirements, this control equipment must have an EtO control efficiency of 99 percent or more during the sterilizer exhaust phase (vacuum pump emissions). The emission-control device met this requirement.

The test results are summarized in Table 1. These tables include results for EtO control efficiency of the emission-control device. Chromatograms and chromatographic supporting data are attached as Appendices A through D. Copies of field data and calculation worksheets are attached as Appendix E.

TABLES

APPENDICES

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Calibration Data

APPENDIX B

Run#1 Chromatograms

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APPENDIX C

Run#2 Chromatograms

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APPENDIX D

Run#3 Chromatograms

APPENDIX E

Field Data and Calculation Worksheets

APPENDIX F
Gas Certifications

APPENDIX G

Process/Parametric Monitoring Data